Paper No. 42

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte RONALD M. EVANS,
CARY A. WEINBERGER,
STANLEY M. HOLLENBERG,
VINCENT GIGUERE,
JEFFREY ARRIZA,
CATHERINE C. THOMPSON, and
ESTELITA S. ONG

Appeal No. 2001-2584[1]
Application No. 08/462,817

Heard: June 27, 2002

Before WILLIAM F. SMITH, SCHEINER, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

VACATUR and REMAND TO THE EXAMINER

Having reviewed the record in this appeal, we have determined that the rejections under 35 U.S.C. §§ 112, first paragraph, 102 and 103 are not based upon the correct legal standards. Accordingly we vacate[2] the rejections of record. In addition, there are a number of issues that need to be clarified by the

[1] This appeal is related to Appeal No. 2001-1582 (Application No. 08/464,574). Accordingly, we have considered these two appeals together.

[2] Lest there be any misunderstanding, the term "vacate" in this context means to set aside or to void. When the Board vacates an examiner's rejection, the rejection is set aside and no longer exists. Therefore the issues set forth herein cannot be satisfied by a Supplemental Examiner's Answer. See Ex parte Zambrano, 58 USPQ2d 1312, 1313 (Bd. Pat. App. & Int. 2000).

examiner. Therefore, we remand the application to the examiner to consider the following issues and take appropriate action.

Claims 47 and 58 are illustrative of the subject matter on appeal and are reproduced below:

> 47. A recombinant expression system for production of functional steroid receptor protein(s), which comprises host cells containing exogenous DNA encoding said protein(s), and wherein the DNA is operably linked to control sequences compatible with said host cell.
>
> 58. A recombinant expression system for production of functional members of steroid/thyroid hormone receptor superfamily of protein(s), said system comprising host cells containing exogenous nucleic acid encoding a protein having hormone binding and/or transcription activating properties of a member of the steroid/thyroid hormone receptor superfamily, wherein said exogenous nucleic acid is operably linked to control sequences compatible with said host cells.

Claim 49 depends from claim 48, which in turn depends from claim 47. Claim 48 adds a further limitation wherein the host cells are mammalian, and claim 49 further limits the mammalian host cells of claim 48 to CV-1 cells. In addition, claim 60 depends from claim 58 and adds the further limitation wherein the host cells are CV-1 cells.

The examiner relies upon the following reference:

Green et al., (Green), "Human oestrogen receptor cDNA: sequence, expression and homology to v-erb-A," Nature, Vol. 320, pp. 134-139 (1986)

GROUNDS OF REJECTION

Claims 47-49, 52 and 56-64 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the scope of the claimed invention.

Claims 47, 48, 56-60, 63 and 64 stand rejected under 35 U.S.C. § 102(a) as anticipated by Green.

Claims 49 and 61[3] stand rejected under 35 U.S.C. § 103 as being unpatentable over Green.

We vacate the rejections and remand this application to the examiner to reevaluate the question of patentability using the proper legal standards.

DISCUSSION

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

According to the examiner (Answer, page 3), "the disclosure is enabling only for claims limited to the production of a functional steroid hormone receptor having of [sic] the amino acid sequence which is disclosed in the instant specification…." In support of this position, the examiner finds (Answer, bridging sentence, pages 3-4):

> The specification does not provide an adequate written description and an enabling disclosure for the construction and use of an expression system encoding any and all proteins which might be encompassed by the term "steroid receptor protein" or for any and all members of a specific class (i.e.[,] estrogen) of steroid receptor proteins.

[3] It appears that the examiner made a typographical error by referencing (Answer, page 8) claim 61 as part of this rejection. Since this rejection is concerned with CV-7 cells, it appears that the examiner intended to reject claim 60, which as discussed above adds, to claim 58, a further limitation "wherein the host cells are CV-1 cells." Claim 61 does not include a limitation drawn to CV-1 cells. Therefore, this typographical error was corrected herein.

As the examiner develops his argument on pages 3-8 of the Answer, he blurs the distinction between the written description and enablement provisions of 35 U.S.C. § 112, first paragraph. By blurring the issues the examiner has introduced substantial confusion into this record. For example, in response to the examiner's position appellants argue that (Brief, page 8) "the [e]xaminer's reliance on … [University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 Fed. Cir. 1997] to support his assertion of non-enablement is erroneous [because] … the key issue addressed by the Federal Circuit [in Lilly] was the issue of written description." In response, the examiner states (Answer, page 9):

> The rejection was originally articulated in section 3 of Paper Number 6, where it was stated that the "[]specification does not provide an adequate written description and an enabling disclosure" for the claimed invention. Therefore, the reliance upon the decision from UC v. Lilly in support of the instant rejection is perfectly proper.

However, in contrast to what the rejection may have been in Paper No. 6, the rejection presented to this Merits Panel is one of enablement. As set forth in Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561, 19 USPQ2d 1111, 1115 (CAFC 1991), "[w]ith respect to the first paragraph of §112 the severability of its "written description" provision from its enablement ("make and use") provision was recognized by this court's predecessor, the Court of Customs and Patent Appeals, as early as In re Ruschig, 379 F.2d 990, 154 USPQ 118 (CCPA 1967)."

To satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, a patent application must adequately disclose the claimed invention so as to enable a person skilled in the art to practice the invention at the time the application was filed without undue experimentation. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371-72, 52 USPQ2d 1129, 1136 (Fed. Cir. 1999). We note, however, "nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). As set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

To assist the fact finder in meeting his initial burden of setting forth a reasonable explanation as to why he believes the scope of the claimed invention is not adequately enabled by the description, our appellate reviewing court has outlined a number of factors that should be considered. As set forth in In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988), the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the

state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

On this record, the examiner provides no analysis of the Wands factors. In addition, we find that the examiner did not rely on any factual evidence to support his position. Instead, we find only the examiner's unsupported conclusions, tied together with the issue of written description, as to why the specification does not enable the claimed invention. In the absence of a fact-based statement of a rejection based upon the relevant legal standards, the examiner has not sustained his initial burden of establishing a prima facie case of non-enablement.

As the examiner recognizes (Answer, page 4), the specification describes seven proteins identified as members of the steroid/thyroid hormone receptor superfamily. In addition, as appellants argue (Brief, page 6):

> Figure III-6 [of the specification] … provides a schematic comparison of steroid and thyroid hormone receptors, and shows areas of homology that define members of the superfamily…. Indeed, it is the presence of such structural domains, which [a]ppellants have identified as existing in all members of the steroid/thyroid hormone superfamily of receptor proteins, and associated functional properties, that defines this family.

According to appellants (Brief, page 7), not only does their specification provide sequence information for several members of the steroid/thyroid receptor superfamily, it also provides a description of the characterizing structural features.

As recognized by the court in Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs

> defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

See also Reply Brief, page 7. By failing to apply the correct legal standards for the issue of enablement and written description the examiner failed to adequately develop the record with regard to either provision of 35 U.S.C. § 112, first paragraph. Most significantly, the examiner failed to clearly explain why the sequence information, provided in appellants' specification, for several members of the steroid/thyroid receptor superfamily, coupled with the description of the characterizing structural features common to receptors in this superfamily is not sufficient to enable, or provide written descriptive support, for the entire receptor superfamily. Accordingly, we vacate the rejection under 35 U.S.C. § 112, first paragraph and remand the application to the examiner for further consideration.

If after review of the specification, prosecution history, and relevant prior art, the examiner believes that a rejection is necessary, the examiner should issue an appropriate Office Action setting forth such a rejection, using the proper legal standards, and clearly setting forth the facts relied upon in support of such a rejection. Any further communication from the examiner that contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

THE REJECTION UNDER 35 U.S.C. § 102(a):

The examiner finds (Answer, page 8) Green, at figure 5 on page 138, describes "a system, cell and method which expressly met all of the limitations of the instant claims prior to the making of the instant invention."

The publication date of the Green reference is March 13, 1986. The instant application was filed on June 5, 1995. However, through a number of divisional applications (08/165,708 (filed December 10, 1993), 07/667,602 (filed March 7, 1991), 07/108,471 (filed October 20, 1987)) the application receives benefit of an effective filing date of, at least, October 20, 1987. The 07/108,471 application, however, is a continuation-in-part of Application No. 06/922,585 (filed October 24, 1986). Therefore, unless appellants are entitled to benefit of the 06/922,585 application of which the present application is a continuation-in-part, the Green reference is available as prior art under 35 U.S.C. § 102(b).

There is, however, no evidence on this record that the examiner performed the necessary fact-finding to determine if appellants' original application, 06/922,585, can support the claims now on appeal. Upon return of the application, the examiner should consider the 06/922,585 application to determine if, in fact, it provides support for the claims as they now appear.

Assuming for the basis of this opinion, that appellants' are entitled to the October 24, 1986 effective filing date, we note that in response to the examiner's rejection, appellants argue (Brief, page 9), "[a] declaration (pursuant to Rule 131) was submitted by all seven inventors … clearly demonstrating that the invention described herein was conceived and reduced to practice in the United States prior to the effective date of the reference…."

The examiner, however, maintains his rejection of the claimed invention, finding (Answer, page 10) support for his position in a quote (Answer, page 9) from In re Clarke, 356 F.2d 987, 961, 148 USPQ 665, 670 (CCPA 1966), citing

In re Soll, 97 F.2d 623, 38 USPQ 189 (CCPA 1938); In re Wahlforss, 117 F.21 270, 48 USPQ 397 (CCPA 1941), "[i]t appears to be well settled that a single species can rarely, if ever, afford support for a generic claim." On the surface, by quoting this particular section from Clarke, it would appear that the examiner is concerned that appellants have not provided evidence of a sufficient number of species to represent a genus. This is, however, inconsistent with the examiner's position (Answer, page 10), that Green

> can only be antedated by showing that [a]pplicant[s], prior to the publication of Green et al., had reduced to practice the now-claimed genus, or a species of the now-claimed genus which would have rendered the species described by Green et al. to have been obvious. … [T]he novelty of the instant invention is found in the "exogenous DNA" encoding the "steroid receptor protein. Applicant has failed to explain how the reduction to practice of an isolated cDNA encoding a human glucocorticoid receptor would have rendered obvious the isolated cDNA encoding the estrogen receptor of Green et al.

The inconsistency in the examiner's position is highlighted by appellants' response (Reply Brief, bridging paragraph, pages 8-9), where with reference to In re Tanczyn, 347 F.2d 830, 146 USPQ 298 (CCPA 1965); In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970); and The Manual of Patent Examining Procedure (MPEP), appellants argue:

> [A] 37 CFR 1.131 affidavit or declaration must establish possession of either the whole invention claimed or something falling within the claim (such as a species of a claimed genus), in the sense that the claim as a whole reads on it. … If the affidavit contains facts showing a completion of the invention commensurate with the claims and as shown in the reference, the affidavit or declaration is sufficient, whether or not it is a showing of the identical disclosure of the reference.

It appears, from this argument, that appellants' are addressing the examiner's quotation from Clarke, explaining that in an appropriate case a single species could be sufficient to antedate indirectly a different species of a reference. See Reply Brief, page 9, "[a]ppellants submit that one need not provide every species of the claimed invention by way of a 37 CFR [sic] § 1.131 Declaration…."

With regard to the examiner's second argument (Answer, page 10), reproduced above, the examiner is attempting to shift his burden to appellants to "explain how the reduction to practice of an isolated cDNA encoding a human glucocorticoid receptor would have rendered obvious the isolated cDNA encoding the estrogen receptor of Green et al." Appellants, however, explain (Brief, page 11) that the glucocorticoid receptor is a species within the genus of receptor proteins set forth in appellants' claimed invention, as is (as the examiner has found) the estrogen receptor. In our opinion, it is the examiner who has failed to meet his burden, in the first instance, of establishing the facts necessary to demonstrate that the evidence supplied by appellants is insufficient to overcome the rejection.

Accordingly, we vacate this rejection and remand the application to the examiner to first determine whether each claim in the pending application is supported by and thereby entitled to benefit of the filing date of appellants' 06/922,585 application. After this determination is made, the examiner should step back and consider the specification and prosecution history (including any declarations provided by appellants), together with the relevant prior art. If the examiner believes that a rejection is necessary, the examiner should issue an

appropriate Office Action setting forth such a rejection, using the proper legal standards and clearly setting for the facts relied upon in support of such a rejection. Furthermore, any such Action that relies on Green should clearly articulate why evidence set forth in appellants' declaration is not sufficient to antedate the Green reference. We emphasize that any further communication from the examiner that contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

THE REJECTION UNDER 35 U.S.C. § 103:

According to the examiner (Answer, page 8), the claimed invention differs from Green only with regard to the choice of host cell employed, Green teaches the use of "HeLa cells whereas the instant claim[s] is [sic] limited to CV-7 cells." To make up for this deficiency in Green the examiner finds (id.), "[t]he use of CV-7 cells … was old and well known in the art at the time that the instant invention was made." The examiner, however, provides no evidentiary support for this position.

In reviewing the Board's findings and conclusions on appeal, the Federal Circuit has stated that "[f]or judicial review to be meaningfully achieved within these strictures[4], the agency tribunal must present a full and reasoned explanation of its decision. The agency tribunal must set forth its findings and the

[4] "5 U.S.C. §706(2) The reviewing court shall—
(2) hold unlawful and set aside agency actions, findings, and conclusions found to be—
(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
* * * *

grounds thereof, as supported by the agency record, and explain its application of the law to the found facts." In re Lee, 277 F.3d 1338, 1342, 61 USPQ2d 1430, 1432-3 (Fed. Cir. 2002). "The agency tribunal must make findings of relevant facts, and present its reasoning in sufficient detail that the court may conduct meaningful review of the agency action." Id. at 277 F.3d 1346, 61 USPQ2d 1435. "Remand for these purposes is required." Id. at 277 F.3d 1346, 61 USPQ2d 1436."

Since the Board also serves as a board of review, not a de novo examination tribunal (35 U.S.C. § 6(b)), in order for the Board to make a meaningful review of the rejections on appeal, the examiner likewise must present a full and reasoned explanation in support of the final rejection. As we explain supra, that has not been done on this record. Accordingly, we vacate the rejection and remand the application to give the examiner a new opportunity to more thoroughly present the grounds of rejection. If the opportunity is taken, the examiner should consider amending the grounds of rejection to support the examiner's finding (Answer, page 8), that "[t]he use of CV-7 cells to obtain expression of human protein in a non-human background to permit the characterization of that protein was old and well known in the art at the time that the instant invention was made."

OTHER ISSUES

> (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute;"

In re Lee, 277 F.3d 1338, 1342, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002).

Upon consideration of co-pending Application No. 08/464,574 (Appeal No. 2001-1582) we find two rejections that may be applicable to the present claims. For clarity we reproduce claims 47 and 51 of co-pending application 08/464,574 below:

> 47. Isolated DNA encoding a member of the steroid/thyroid hormone receptor superfamily, wherein said member has an N-terminal domain, a DNA binding domain and a ligand binding domain, and wherein said DNA binding domain is a cysteine-rich domain comprising 66 amino acid residues.
>
> 51. An expression vector containing DNA according to claim 47.

In co-pending Application No. 08/464,574 the examiner found claim 51 to have been obvious over the combination of Walter in view of Leonard. According to the examiner in that application, Walter teach, inter alia, a human estrogen receptor, and Leonard teach, inter alia, an expression vector and host cell. See 08/464,574, Answer, pages 8-10. It appears that this rejection is applicable to the claims on appeal in this application.

Furthermore, in co-pending application 08/464,574 the examiner rejected all the claims under the judicially created doctrine of obviousness-type double patenting over claims 1-23 of U.S. Patent No. 5,312,732. Claims 1 and 17 of U.S. Patent No. 5,312,732 read as follows:

> 1. Recombinant DNA capable of hybridizing with DNA encoding protein having the amino acid sequence shown in FIG. IV-2(B) (hMR), FIG. V-1(B) (hERR1), or FIG. V-2(B) (hERR2), or DNA complementary thereto, under low stringency hybridization conditions, wherein said DNA encodes functional receptor protein(s) having hormone-binding and/or transcription activating properties of mineralocorticoid receptor, estrogen-related receptor hERR1 or estrogen-related receptor hERR2.

17. A recombinant expression system for production of functional steroid receptor protein(s) selected from mineralocorticoid receptor, hERR1 or hERR2, wherein said system comprises host cells containing DNA encoding said receptor protein(s), and wherein the DNA is operably linked to control sequences compatible with said host cells.

It is unclear why the examiner did not raise a similar obviousness-type double patenting rejection over the claims in this application.

Prior to any further action, the examiner should consider whether the forgoing actions taken in co-pending Application No. 08/464,574 are applicable to the claims on appeal in the present application.

We are not authorizing a Supplemental Examiner's Answer under the provisions of 37 CFR § 1.193(b)(1). Any further communication from the

examiner that contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

VACATED and REMANDED

William F. Smith Administrative Patent Judge	))))) BOARD OF PATENT
Toni R. Scheiner Administrative Patent Judge	)) APPEALS AND)) INTERFERENCES
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